CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SUBURBAN MEDICAL LABORATORY, INC., AND
PH MEDICAL LABORATORY, INC.

I. PREAMBLE

Suburban Medical Laboratory, Inc., and PH Medical Laboratory, Inc. (collectively, "Laboratories") hereby agree to enter into this Corporate Integrity Agreement (the "Agreement" or "CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance with the requirements of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Laboratories, its employees and all third parties with whom Laboratories may choose to engage to act as billing or coding agents or consultants for Laboratories. On or about this date, Laboratories are entering into a settlement agreement with the United States and this CIA is incorporated by reference into that settlement agreement.

II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by Laboratories under this CIA shall be three (3) years from the date of execution of this CIA (unless otherwise specified).

III. CORPORATE INTEGRITY OBLIGATIONS

a. Compliance Committee and Compliance Officer. Within ninety (90) days of the date of execution of this Agreement, the Board of Directors of Laboratories shall: (i) direct the creation of a Corporate Compliance Committee (the "Compliance Committee"); (ii) charge the Compliance Committee with the responsibility to establish and implement the Program; and (iii) appoint an individual or individuals to serve as Laboratories' Compliance Officer(s). The members of the Compliance Committee shall, at a minimum, include the Compliance Officer(s), and other appropriate individuals, e.g., the President of Laboratories, a member of the Board of Directors, and a representative of the billing department. The Compliance Officer shall chair the Compliance Committee and shall be responsible for developing, implementing, monitoring, adapting, reporting on, and certifying compliance with, policies and procedures and practices designed to ensure compliance with the requirements set forth in this CIA, and with the requirements of Medicare, Medicaid, and all other Federal health care programs.

b. Policies and Procedures. Within 90 days after the execution of this CIA, Laboratories shall develop and effectively implement written Policies and Procedures

regarding compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of Medicare, Medicaid, and other Federal health care programs. The Policies and Procedures shall include disciplinary guidelines and methods for employees to make complaints and notifications about compliance issues to Laboratories management through the Confidential Disclosure Program required by section III(e). Laboratories shall update the Policies and Procedures at least annually and more frequently as appropriate. The Policies and Procedures shall be distributed by Laboratories individually to all employees, all contractors, and to all other individuals affected by them. Within 90 days after the execution of this CIA, or within one week after the commencement of the individual's relationship with Laboratories (e.g., employment or contract), whichever is later, and annually thereafter, each individual who should receive the Policies and Procedures shall certify that he or she has read and understands the Policies and Procedures. Laboratories shall keep a copy of these certifications on file for at least one year after the completion of the corporate integrity period mandated by this CIA.

c. Training and Education. Within 90 days after execution of this CIA, Laboratories shall require and provide at least two hours of training to each and every employee of Laboratories with responsibility for the provision, documentation, or billing of clinical laboratory services. This general training shall: (1) cover Laboratories's Policies and Procedures; (2) reinforce the need for strict compliance with the applicable

statutes, regulations, policies, procedures, and program guidelines, and Laboratories's Policies and Procedures; and (3) advise employees that any failure to comply may result in disciplinary action. Annually thereafter, Laboratories shall require and provide one hour of such training to such individuals. New employees shall receive the general training described above within one week of the beginning of their employment or within 90 days after the execution of this CIA, whichever is later. In addition to the general training described above, within one week of the beginning of their employment or within 90 days after execution of this CIA, whichever is later, each and every person involved in the submission of claims to Medicare, Medicaid, or any other Federal health care programs shall receive at least three hours of training regarding the applicable statutes, regulations, policies, procedures, and program guidelines for Medicare, Medicaid, and all other Federal health care programs. If a person has any responsibility for the assignment of diagnosis or procedure codes prior to completing this coding training, a Laboratories employee who has completed the coding training shall review all of the untrained person's work regarding the assignment of diagnosis or billing codes. Annually thereafter, Laboratories shall require and provide two hours of the above described coding training to such individuals.

d. Audits and Disclosures. Annually, prior to the first, second, and third anniversaries of the execution of this CIA, Laboratories shall perform through qualified personnel, or retain a third-party to perform, audits in the form of a statistically valid

sample of claims designed to ensure compliance with the written Policies and Procedures described in III(b), with this CIA, and with all applicable federal and state health care statutes, regulations, policies, procedures, and program requirements. Such audits should cover areas of potential fraud, abuse, or waste, as identified by Laboratories or by the government. The audits must be retained by Laboratories for at least one year after the completion of the corporate integrity period mandated by this CIA. If, as a result of these audits or through any other means, Laboratories discovers any billing, coding or other policies, procedures and/or practices that result in a material deficiency, Laboratories shall notify the payor (e.g, Medicare carrier) within 30 days of discovering the deficiency and take remedial steps within 60 days (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the deficiency from reoccurring. The notice to the payor should state that the repayment is being made in accordance with the terms of this CIA and should include: (1) the methodology by which the overpayment was determined; (2) any claim specific information used to determine the overpayment; and (3) the amount of the overpayment; and (4) the date of the check and check number (or electronic transaction number) on which the overpayment was repaid. For purposes of this CIA, a "material deficiency" shall mean anything that has a significant, adverse financial impact upon the Medicare and/or Medicaid programs, which may be the result of an isolated event or a series of occurrences, and which lacks conformity with Medicare and/or Medicaid reimbursement principles or other applicable statutes, and the

regulations and written directives issued by the Health Care Financing Administration ("HCFA") and/or its agents, or any other agency charged with administering the health care program implicated and/or its agents. Contemporaneous with Laboratories' notification to the payor as provided above, Laboratories shall notify OIG of: (1) all of the information provided to the carrier in returning the overpayment; (2) the name and the address of the carrier where the overpayment was sent; (3) Laboratories' findings concerning the material deficiency; (4) Laboratories' actions to correct such material deficiency; and (5) any further steps the Laboratories plans to take to address such material deficiency and prevent it from reoccurring. While this reporting requirement focuses on occurrences having a "significant, adverse financial impact," this provision does not excuse the Laboratories' statutory obligation as a Medicare or Medicaid participant to bring to a payor's attention any other billing deficiencies, however de minimis, make appropriate refunds and take any steps necessary to prevent the occurrence in the future. In the event that the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which Laboratories is complying with its obligations under this CIA, Laboratories agree to pay for the reasonable cost of any such review. If as a result of the OIG review it is determined that an independent audit is necessary, Laboratories agree to pay for the reasonable costs of the audit.

e. Confidential Disclosure Program. Within 90 days after the execution of this CIA, Laboratories shall establish a Confidential Disclosure Program enabling employees, and agents and contractors, if applicable, to communicate about compliance issues to the Compliance Officer. The Confidential Disclosure Program shall include methods, such as a toll-free compliance "hotline," for employees, agents, and contractors to disclose any practices or procedures with respect to Medicare, Medicaid, or any other Federal health care program, alleged by the individual to be inappropriate, to the Compliance Officer or some other person who is not in the reporting individual's chain of command. The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Laboratories shall use intake procedures designed to elicit all relevant information from individuals reporting alleged misconduct. For any disclosure that is sufficiently specific that it reasonably (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides opportunity for the taking of corrective action, Laboratories shall require the internal review of the allegations set forth in such disclosure and ensure that proper follow-up is conducted. Laboratories shall, in good faith, make a preliminary inquiry into the allegations set forth in every disclosure to ensure that it has obtained all of the information necessary to determine whether it should conduct an internal review as provided above. The Compliance Officer shall maintain a confidential disclosure log, which shall include a record of each allegation received,

status of the investigation of the allegation, and any corrective action taken in response to the investigation. The Compliance Officer shall maintain all documentation related to information in the log and make such documents available for inspection by the OIG upon request.

f. Excluded Individuals. Effective upon the date of execution of this CIA, Laboratories shall not employ, contract with, or otherwise use the services of any individual whom Laboratories know or should have known, after reasonable inquiry, (a) has been convicted of a criminal offense related to health care (unless the individual has been reinstated to participation in Medicare after being excluded because of the conviction), or (b) is currently listed by a federal agency as excluded, debarred, or otherwise ineligible for participation in any Federal health care program. In furtherance of this requirement, Laboratories agree to make reasonable inquiry as to any individual who is a prospective employee, agent, or individual considered for engagement by Laboratories as an independent contractor by reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available over the internet at http://www.arnet.gov/epls) and the HHS/OIG Cumulative Sanction Report (available over the internet at http://www.dhhs.gov/progorg/oig).

IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, contract or pursuant to this CIA, OIG or its duly authorized representative(s) may examine

Laboratories' books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (i) Laboratories' compliance with the terms of this CIA; and (ii) Laboratories' compliance with the requirements of the Medicare, Medicaid and other federal health care programs. The documentation described above shall be made available by Laboratories at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its authorized representative(s) may interview any of Laboratories' employees who consents to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG. Laboratories agree to assist OIG in contacting and arranging interviews with such employees upon OIG's request. Laboratories' employees may elect to be interviewed with or without a representative of Laboratories present.

V. INITIAL AND ANNUAL REPORTS

Within 120 days after the execution of this CIA, Laboratories shall submit a written report to the OIG. This initial report shall include: (1) the name and position description of the Compliance Officer described in III(a); (2) the written Policies and Procedures required by III(b); and (3) a description of the training programs implemented pursuant to III(c) and a summary of the activities undertaken in furtherance of the training programs, including schedules and topic outlines from the training sessions. Thereafter, Laboratories shall submit to the OIG a written report annually within 30 days after the

first, second, and third anniversary dates of the execution of this CIA, with respect to the status and findings of Laboratories' compliance activities. The annual reports shall include: (1) any change in the identity or position description of the Compliance Officer described in III(a); (2) any changes or amendments to the Policies and Procedures required by III(b); (3) a description of any changes in the training programs implemented pursuant to III(c) and a summary of the activities undertaken in furtherance of the training programs, including schedules and topic outlines for the training sessions; (4) a description of the audits conducted pursuant to III(d), their results, problems identified in the audits, and corrective actions taken to address those problems; (5) a description of the disclosures received and actions taken by Laboratories pursuant to III(e) and a copy of the a confidential disclosure log required by that section; (6) a description of any personnel action taken by Laboratories as a result of the obligations in section III(f); (7) a description of any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Laboratories have committed a crime or have engaged in fraudulent activities; (8) a report of the aggregate overpayment that have been returned to the Medicare program that were discovered as direct or indirect result of the corporate integrity provisions in this CIA (the report must include a detailed description of how the overpayments were calculated); and (9) a certification by the Compliance Officer verifying that Laboratories are in compliance with all of the requirements of this CIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this CIA, all notifications and reports required under the terms of this CIA shall be submitted to the entities listed below:

If to the OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

If to Laboratories:

Dr. Sandra Fishel
Suburban Medical Laboratory
111 Stow Avenue
Cuyahoga Falls, Ohio 44221
Tel.: 330-929-7992

VII. DOCUMENT AND RECORD RETENTION

Laboratories shall maintain for inspection documents and records relating to reimbursement from the federal health care programs or with compliance with this CIA until the fourth anniversary of the execution of this CIA or until otherwise required to retain such records, whichever is later.

VIII. BREACH AND DEFAULT PROVISIONS

Laboratories' compliance with the terms and conditions in this CIA shall constitute an element of Laboratories' present responsibility with regard to participation in Federal health care programs. Full and timely compliance by Laboratories shall be expected throughout the duration of the compliance period required by this CIA with respect to all of the obligations herein agreed to by Laboratories. All modifications to this CIA (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by the OIG in writing prior to the date on which the modification is expected to take effect.

A. STIPULATED PENALTIES FOR FAILURE TO COMPLY WITH CERTAIN OBLIGATIONS

As a contractual remedy, Laboratories and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "stipulated penalties") in accordance with the following provisions.

1. A stipulated penalty of $1,500 (which shall begin to accrue on the date the obligation became due) for each day Laboratories fails to have in place any of the following during the entire period beginning 90 days after the execution of this CIA and concluding at the end of the corporate integrity period required by this CIA:

   a. a Compliance Officer;

b. written Policies and Procedures;

c. an education and training program;

d. a mechanism for obtaining compliance audits and reporting material deficiencies; and

e. a Confidential Disclosure Program;

(2) A stipulated penalty of $1,500 (which shall begin to accrue on the date the obligation became due) for each day Laboratories fails meet the deadline set forth in section III(g) to provide a written report within 120 days of the execution of this CIA and submission of annual written reports within 30 days of the first, second, and third anniversary dates of the execution of this CIA.

(3) A stipulated penalty of $1,500 (which shall begin to accrue on the date the failure to comply began) for each day Laboratories employs or contracts with an individual after that individual has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)). This stipulated penalty shall not be demanded if Laboratories can demonstrate that they did not discover the individual's exclusion or other ineligibility after making a reasonable

inquiry (as described in section III(f)) as to the current or potential status of the employee or consultant engaged.

(4) A stipulated penalty of $1,500 (which shall begin to accrue on the date that the OIG provides notice to Laboratories of the failure to comply) for each day Laboratories fail to comply with any corporate integrity requirement in this CIA where the failure to comply does not form the basis for stipulated penalties under provisions (1), (2), or (3) above.

B. PAYMENT OF STIPULATED PENALTIES

(1) Upon finding that Laboratories have failed to comply with any of the obligations described in section A and determining that stipulated penalties are appropriate, the OIG shall notify Laboratories by certified mail of: (i) Laboratories' failure to comply; and (ii) the OIG's exercise of its contractual right to demand payment of the stipulated penalties (this notification is hereinafter referred to as the "Demand Letter"). Within 15 days of the date of the Demand Letter, Laboratories shall either: (i) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; (ii) request a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section D of this section; or (iii) be in material breach of this CIA.

(2) Laboratories may submit a timely written request for an extension of time to perform any act or file an notification or report required by this CIA. Notwithstanding

any other provision in this section, if OIG grants the timely written request, Stipulated Penalties shall not begin to accrue unless and until Laboratories fail to meet the deadline granted by the extension. Notwithstanding any other provision in this section, if OIG denies a timely written request, Stipulated Penalties shall not begin to accrue until two business days following Laboratories' receipt of OIG's written denial of such an extension. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or notification or report is due to be filed.

(3) Payment of the stipulated penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to the OIG at the address set forth in section III(g).

(4) Except as otherwise noted, these provisions for payment of stipulated penalties shall not affect or otherwise set a standard for the OIG's determination that Laboratories has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section C of this section, below.

C. EXCLUSION FOR MATERIAL BREACH OF THIS CIA

The parties agree that a material breach of this CIA by Laboratories constitutes an independent basis for Laboratories' exclusion from participation in Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by the OIG that Laboratories has materially breached this CIA and that

exclusion should be imposed, the OIG shall notify Laboratories by certified mail of: (i) Laboratories' material breach; and (ii) the OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude Letter"). Laboratories shall have 35 days from the date of the letter to proceed as follows:

(1) demonstrate to the OIG's satisfaction that Laboratories are in full compliance with this CIA;

(2) cure the alleged material breach; or

(3) demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the 35 day period, but that (i) Laboratories have begun to take action to cure the material breach, (ii) Laboratories are pursuing such action with due diligence, and (iii) Laboratories have provided to the OIG a reasonable timetable for curing the material breach.

If at the conclusion of the 35-day period (or other specific period as subsequently agreed by OIG and Laboratories), Laboratories fail to meet the requirements of provisions 1, 2, or 3 above, OIG may exclude Laboratories from participation in the Medicare, Medicaid and any other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). OIG will notify Laboratories in writing of its determination to exclude Laboratories (this letter shall be referred to hereinafter as the "Exclusion Letter"). The exclusion shall have national effect and will also apply to all other federal procurement

and non-procurement programs. If Laboratories are excluded under the provisions of this CIA, Laboratories may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

A material breach of this CIA means: (i) a failure by Laboratories to meet an obligation under this CIA where the failure has a significant adverse impact on the integrity of Medicare, Medicaid, or any other Federal health care program (for example, a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III(d)); or (ii) repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section A of this section.

In connection with the OIG's determination to exclude Laboratories pursuant to this provision, Laboratories shall have the right to dispute the OIG's determination in accordance with the agreed upon provisions set forth in section D of this section.

D. DISPUTE RESOLUTION

Upon the OIG's delivery to Laboratories of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Laboratories shall be afforded some review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the stipulated penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of stipulated penalties or to

seek exclusion shall be subject to review by an ALJ and Departmental Appeals Board (DAB) in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within ten (10) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this CIA shall be: (i) whether Laboratories were in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and, (ii) the period of noncompliance. Laboratories shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. For purposes of paying stipulated penalties under this CIA, and if Laboratories choose to seek review in lieu of curing the breach and paying the stipulated penalties, as set forth above, the ALJ's decision shall trigger Laboratories' obligation to pay. Thus, payment will be due 20 days after the date that the ALJ issues the decision. Laboratories' election of its contractual right to appeal to the DAB shall not excuse its obligation to make payment upon issuance of the ALJ's decision.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on

a breach of this CIA shall be: (i) whether Laboratories were in material breach of this CIA; and (ii) whether such breach was continuing on the date of the Exclusion Letter. For purposes of the exclusion herein agreed to in the event of material breach of this CIA, the ALJ's decision shall trigger the exclusion. Thus, the OIG may proceed with its exclusion of Laboratories if and when the ALJ issues a decision in favor of the OIG. Laboratories' election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Laboratories upon the issuance of the ALJ's decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and agree to waive any right they may have to appeal the decision administratively, judicially or otherwise seek its review by any court or other adjudicative forum.

IX. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the settlement agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Laboratories and the OIG agree as follows:

1. this CIA shall be binding on the successors, assigns and transferees of Laboratories;

2. this CIA shall become final and binding upon signing by each respective party hereto;

3. any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

4. the undersigned Laboratories signatories represent and warrant that they are authorized to execute this CIA. The undersigned United States signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF SUBURBAN MEDICAL LABORATORY, INC., AND PH MEDICAL LABORATORY, INC.

Sandra S. Fishel, M.D.
Suburban Medical Laboratory

9-23-98
DATE

Sandra S. Fishel, M.D.
PH Medical Laboratory

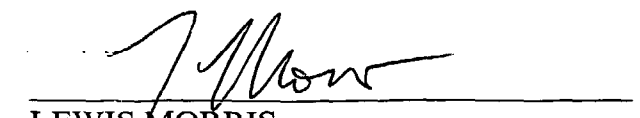
9-23-98
DATE

Ann L. Hunsaker

September 22, 1998
DATE

[Please identify all signatories]

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

9/29/98
DATE